Overview of models for technology transfer (private-sector-driven vs. developing country or donor-driven)

International Vaccine Technology Workshop

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Goal-Increase skills and capacity of developing country vaccine manufacturers

- Drivers
  - Reduce costs
  - Increase profits
  - Increase global capacity
  - Increase affordability/availability for resource-poor countries
  - Increase self-reliance (developing countries)
  - Improve ability to mount global response to future infectious disease threats

Important considerations regarding technology transfer for biological products

- Almost all biological products are defined, in large part, by the manufacturing process
- Manufacturing process nearly impossible to exactly duplicate from one facility to another
- Technology transfer is more time consuming and difficult than most organizations anticipate (transferer and transferee)
- Clinical bridging studies almost always required-size and rigor dependent upon NRA of transferee (and NRAs of external markets)

Prior and current models of technology transfer

- Multinational pharmaceutical company to developing country vaccine manufacturer
  - rHepB vaccine (Merck to China)
  - Seasonal inactivated flu vaccine (Sanofi Pasteur to Butantan, Brazil)
- Meningococcal GpA conjugate vaccine (PATH/US FDA to Serum Institute of India)
- Inactivated flu vaccine (WHO/Netherlands Vaccine Institute (hub) to various developing country vaccine manufacturers)

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